

Clinical Policy: Low-Frequency Ultrasound and Noncontact Normothermic Wound Therapy

Reference Number: PA.CP.MP.139

Date of Last Revision: 03/23

Coding Implications

Revision Log

Description

Low-frequency ultrasound debridement is a noncontact debridement method that provides simultaneous cleansing and debridement of wounds. It is generally performed at a five mm to 15 mm distance from the wound surface. A device uses ultrasound technology to atomize saline, delivering a continuous mist to the treatment site. Multiple passes over the wound are made with the treatment head of the device for a predetermined treatment session. This can accelerate the wound healing process by removing the necrotic tissue, fibrosis, exudate, and bacteria with minimum bleeding and pain.

Noncontact normothermic wound therapy (NNWT) utilizes radiant heat to provide an optimal environment for wound healing by maintaining 100% relative humidity and warming to normothermia in the wound bed.

Policy/Criteria

- I. It is the policy of health plans affiliated with PA Health & Wellness® that current evidence does not support the use of low-frequency ultrasound wound therapy.
- II. It is the policy of health plans affiliated with PA Health & Wellness that current evidence does not support the use of noncontact normothermic wound therapy (NNWT).

* It is the policy of PA Health & Wellness® (PHW) that determinations for services that are considered **not medically necessary** must be considered on a case-by-case basis by a physician or ad hoc committee and must be made in accordance with the Benefit Plan Contract provisions and applicable state and federal requirements. Denials will require medical director review.

Background

The treatment of chronic and difficult to heal wounds presents many clinical challenges. To ensure proper healing, the wound bed needs to be well vascularized, free of devitalized tissue, clear of infection, and moist. Surgical debridement is the most appropriate choice for removing large areas of necrotic tissue and is indicated whenever there is any evidence of infection (e.g., cellulitis, sepsis).^{1,6} Surgical debridement is also indicated in the management of chronic non-healing wounds to remove infection, manage undermined wound edges, or obtain deep tissue for culture and pathology.¹

Low-frequency Ultrasound Wound Therapy

Noncontact, low-frequency ultrasound debridement devices have been proposed as adjunctive treatment of a variety of wounds including, but not limited to, acute, traumatic, chronic, and dehisced wounds. Several devices have received FDA approval, including but not limited to, The Mist Therapy System (Alliqua Biomedical), Qoustic Wound Therapy System (Arobella Medical, LLC), SonicOne Ultrasonic Wound Debridement System (Misonix Inc.) and Sonoca TM 180/1

96 Wound Care System. Evidence for the use of these devices to treat wounds is limited and consist of studies that lack adequate sample sizes. Results at this time are inconclusive.

A Cochrane database review of randomized control trials (RCTs) comparing ultrasound with no ultrasound in wound care identified two trials evaluating low frequency ultrasound. The trials reported healing at different time points. Both trials reported no evidence of a difference in the proportion of ulcers healed with ultrasound compared with no ultrasound. Both trials were significantly underpowered. The reviewers concluded there is no evidence of a benefit associated with low frequency ultrasound.² Several other small randomized controlled trials that compared patients treated with noncontact low-frequency ultrasound therapy in addition to standard wound care reported that outcome measures favored noncontact low-frequency ultrasound therapy in addition to standard wound care over standard wound care alone. However, the differences were not statistically significant.^{3,4} A small RCT of 35 patients who received MIST Therapy plus the standard of wound care (treatment group) compared to 35 patients who received the standard of wound care alone (control group) for 12 weeks or until fully healed reported that a significantly higher percentage of patients treated with the standard of care plus MIST Therapy achieved greater than 50% wound healing at 12 weeks than those treated with the standard of care alone (63% versus 29%).⁵ Additional research with larger randomized trials is necessary in order to demonstrate that low frequency ultrasound is beneficial for health outcomes in patients with wounds.

National Institute of Health Care Excellence (NICE)

The National Institute of Health Care Excellence (NICE) concluded, “The MIST Therapy system shows potential to enhance the healing of chronic, ‘hard-to-heal’, complex wounds, compared with standard methods of wound management. However, the amount and quality of published evidence on the relative effectiveness of the MIST Therapy system is not sufficient to support the case for routine adoption of the MIST Therapy system. Comparative research is recommended to reduce uncertainty about the outcomes of patients with chronic, ‘hard-to-heal’, complex wounds treated by the MIST Therapy system compared with those treated by standard methods of wound care.”⁶ In June 2016, NICE reviewed the guidance again and decided not to update it, noting new relevant evidence has been published but it is inconclusive.⁶

Society for Vascular Surgery and the American Venous Forum.

The Committee advises against ultrasonic debridement over surgical debridement in the treatment of venous leg ulcers. (Grade 2, Level of Evidence C)⁷

Noncontact Normothermic Wound Therapy

Noncontact normothermic wound therapy (NNWT) devices utilize radiant heat to promote wound healing and reportedly promotes wound healing by warming a wound to a predetermined temperature. The rationale underlying NNWT is that high moisture levels and physiologic temperatures promote wound healing. Physiologic temperature increases blood flow to the affected tissue, thereby increasing oxygenation, which increases collagen deposition, scar formation, and antibacterial processes. It is intended for the management of partial- or full-thickness chronic wounds.^{8,9,10}

A 2011 meta-analysis cited by Centers for Medicare and Medicaid Services (CMS) noted 85% wound-area reduction over an average of seven weeks, wound-volume reduction of 80% at an average of 12 weeks, and 42% complete wound closure at 12 weeks. By comparison, a meta-analysis of standard-of-care treatment found only 24% complete wound closure at 12 weeks demonstrating the efficacy of Noncontact, Low Frequency Ultrasound (NLFU) at achieving almost twice the healing of the standard treatment.¹⁹

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2022, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| CPT® Codes | Description |
|------------|---|
| 97610 | Low frequency, non-contact, non-thermal ultrasound, including topical application(s) when performed, wound assessment, and instruction(s) for ongoing care; per day |

| HCPCS Code | Description |
|------------|---|
| E0231 | Noncontact wound-warming device (temperature control unit, AC adapter and power cord) for use with warming card and wound cover |
| E0232 | Warming card for use with the noncontact wound-warming device and noncontact wound-warming wound cover |

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|---|---------------|---------------|
| Policy developed | 04/18 | 06/18 |
| References reviewed and updated | 02/19 | |
| Annual review, no changes | 10/19 | 01/10/2020 |
| Renamed policy to Low Frequency Ultrasound Therapy and Noncontact Normothermic Wound Therapy for Wound Management. Added criteria and background for noncontact normothermic wound therapy from WellCare policy HS-216 Wound Care. References reviewed and updated. Replaced “members” with “members/enrollees” in all instances. | 2/18/2021 | |
| Annual review. References reviewed and updated. Coding reviewed. Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.” “Experimental/investigational” verbiage replaced in policy statement with descriptive language. Specialist review. | 03/23 | |

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|---|---------------|---------------|
| Annual review. Background updated with no impact on policy statement. References reviewed and updated. | 03/23 | |
| Annual review completed. Background updated. Reworded extraneous language with no clinical significance. References reviewed and updated. External specialist reviewed. Case-by-case review language. | 03/23 | |

References

1. Armstrong DG, Meyr AJ. Basic principles of wound management. UpToDate. www.uptodate.com. Updated June 9, 2022. Accessed February 6, 2023.
2. Cullum NA, Liu Z. Therapeutic ultrasound for venous leg ulcers. *Cochrane Database Syst Rev*. 2017;5(5):CD001180. doi:10.1002/14651858.CD001180.pub4.
3. White J, Ivins N, Wilkes A, Carolan-Rees G, Harding KG. Non-contact low-frequency ultrasound therapy compared with UK standard of care for venous leg ulcers: a single-centre, assessor-blinded, randomised controlled trial. *Int Wound J*. 2016;13(5):833 to 842. doi:10.1111/iwj.12389
4. Olyaie M, Rad FS, Elahifar MA, et al. High-frequency and noncontact low-frequency ultrasound therapy for venous leg ulcer treatment: a randomized, controlled study. *Ostomy Wound Manage*. 2013 Aug;59(8):14 to 20.
5. Kavros SJ, Miller JL, Hanna SW. Treatment of ischemic wounds with noncontact, low-frequency ultrasound: the Mayo clinic experience, 2004-2006. *Adv Skin Wound Care*. 2007;20(4):221 to 6. doi: 10.1097/01.ASW.0000266660.88900.38.
6. The National Institute for Health and Care Excellence. Medical technologies guidance [MTG5] The MIST Therapy system for the promotion of wound healing. <https://www.nice.org.uk/guidance/mtg5>. Published July 25, 2011 (reviewed June 2016). Accessed February 6, 2023.
7. O'Donnell TF Jr, Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery® and the American Venous Forum. *J Vasc Surg*. 2014;60(2 Suppl):3S to 59S. doi:10.1016/j.jvs.2014.04.049.
8. Decision memo for Warm-Up Wound Therapy® a/k/a noncontact normthermic wound therapy (NNWT) (CAG-00114N). Centers for Medicare and Medicaid Services. <http://www.cms.hhs.gov/mcd/search.asp>. Published January 14, 2002 (amended February 14, 2002). Accessed February 6, 2023.
9. National coverage determination: noncontact normothermic wound therapy (270.2). Centers for Medicare and Medicaid Services. <http://www.cms.hhs.gov/mcd/search.asp>. Published July 1, 2002. Accessed February 6, 2023.
10. Gibbons GW, Orgill DP, Serena TE, et al. A prospective, randomized, controlled trial comparing the effects of noncontact, low-frequency ultrasound to standard care in healing venous leg ulcers. *Ostomy Wound Manage*. 2015;61(1):16 to 29.
11. Yao M, Hasturk H, Kantarci A, et al. A pilot study evaluating non-contact low-frequency ultrasound and underlying molecular mechanism on diabetic foot ulcers. *Int Wound J*. 2014;11(6):586 to 93.
12. Driver VR, Yao M, Miller CJ. Noncontact low-frequency ultrasound therapy in the treatment of chronic wounds: a meta-analysis. *Wound Repair Regen*. 2011 Jul-Aug;19(4):475 to 80.

13. Kavros SJ, Liedl DA, Boon AJ, et al. Expedited wound healing with noncontact, low-frequency ultrasound therapy in chronic wounds: a retrospective analysis. *Adv Skin Wound Care*. 2008;21(9):416 to 23. doi:10.1097/01.ASW.0000323546.04734.31.
14. Kavros SJ, Schenck EC. Use of noncontact low-frequency ultrasound in the treatment of chronic foot and leg ulcerations: a 51-patient analysis. *J Am Podiatr Med Assoc*. 2007;97(2):95 to 101. doi: 10.7547/0970095.
15. Ennis WJ, Valdes W, Gainer M, Meneses P. Evaluation of clinical effectiveness of MIST ultrasound therapy for the healing of chronic wounds. *Adv Skin Wound Care*. 2006;19(8):437 to 46. doi: 10.1097/00129334-200610000-00011.
16. Berlowitz D. Clinical staging and management of pressure-induced skin and soft-tissue injury. UpToDate. www.uptodate.com. Updated April 1, 2022. Accessed February 6, 2023.
17. Mathes BM, Kabnick LS. Medical management of lower extremity chronic venous disease. UpToDate. www.uptodate.com. Updated May 31, 2022. Accessed February 6, 2023.
18. Baba-Akbari Sari A, Flemming K, Cullum NA, Wollina U. Therapeutic ultrasound for pressure ulcers. *Cochrane Database Syst Rev*. 2006;(3):CD001275. doi:10.1002/14651858.CD001275.pub2.
19. Local Coverage Determination: Wound care (L37228). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published April 16, 2018 (revised February 24, 2022). Accessed February 6, 2023.
20. Local Coverage Article: Billing and Coding: Low frequency, non-contact, non-thermal ultrasound (A53773). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published October 1, 2015 (revised February 25, 2021). Accessed February 6, 2023.
21. Local Coverage Article: Billing and Coding: Low frequency, non-contact, non-thermal ultrasound (A54555). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published October 1, 2015 (revised February 25, 2021). Accessed February 6, 2023.
22. Local Coverage Article: Billing and Coding :Wound Care and Ulcer Care (A58565). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published November 28, 2021 (revised February 3, 2022). Accessed February 6, 2023.
23. Local Coverage Article: Billing and Coding :Wound Care and Ulcer Care (A58567). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published November 28, 2021(revised February 3, 2022). Accessed February 6, 2023.
24. Local Coverage Article: Billing and Coding: Wound Care (A55818). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published December 7, 2017 (revised February 10, 2022). Accessed February 6, 2023.
25. Local Coverage Article: Billing and Coding: Wound Care (A53001). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published [October 1](#), 2015 (revised February 10, 2022). Accessed February 6, 2023.
26. Local Coverage Article: Billing and Coding: Wound Care (A55909). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published April 16, 2018 (revised May 27, 2021). Accessed February 6, 2023.
27. Local Coverage Article: Low frequency, non-contact, non-thermal ultrasound (CPT code 97610) (A56175). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published November 1, 2018 (revised (March 3, 2022)). Accessed February 7, 2023.